Clinical follow-up compared with self-assessment of outcome after medical abortion: a multicentre, non-inferiority, randomised, controlled trial

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Summary

Background **Medical abortion with mifepristone and prostaglandins is well established. We compared clinical assessment with self-assessment of abortion outcome.**

Methods **This randomised, controlled, non-inferiority trial was done in four clinics in Austria, Finland, Norway, and Sweden, between Aug 16, 2011, and Jan 31, 2013. Women aged 18 years and older who had requested medical termination of a pregnancy up to 63 days of gestation were eligible. Computer-generated block randomisation (block size ten) assigned women in a 1:1 ratio to attend routine clinical follow-up or to self-assess outcome at home with a semiquantitative urine human chorionic gonadotropin (hCG) test 1–3 weeks after abortion. The primary outcome was the percentage of women with complete abortion not requiring further medical or surgical intervention within 3 months. Analysis was per protocol and by intention to treat. The non-inferiority margin was five percentage points. This trial is registered with ClinicalTrials.gov, number NCT01487213.**

Findings **924 women were assigned routine follow-up (n=466) or self-assessment (n=458) and included in the intention-to-treat analysis. 901 were included in the per-protocol analysis (n=446 and n=455, respectively). Complete abortion was reported in 432 (95%) of 455 in the routine follow-up group and 419 (94%) of 446 women in the self-assessment group (crude difference –1·0, 95% CI –4·0 to 2·0). 20 (4%) women in the routine follow-up group and 17 (4%) in the self-assessment group required surgery. No women in the routine follow-up group versus three in the self-assessment group had undetected continuing pregnancies. Eight (1·8%) and one (0·2%) women, respectively, had infections (p=0·038).**

Interpretation **Self-assessment was non-inferior to routine follow-up and could save resources.**

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Introduction

Medical abortion with combined mifepristone and misoprostol has been established as a highly effective, safe, and acceptable method for medical termination of pregnancy for the past 25 years.[1] This method is simpler and requires fewer resources than surgical abortion and provides women with a choice of intervention.

Medical abortion consists of several steps, including misoprostol to take at home, which helps to demedicalise abortion and provides privacy. Women prefer to terminate pregnancy quickly with as few visits to a clinic as possible.[2] Despite the proven efficacy and safety of medical abortion, a need is widely perceived for routine clinical follow-up to exclude continuing pregnancy.[3] If complete abortion can be confirmed, however, international guidelines do not endorse clinical follow-up.[1,4] Routine follow-up might include ultrasonography, measurement of human chorionic gonadotropin (hCG) in serum or urine, and pelvic examination, which could require more than one clinic visit.[5] By contrast, routine follow-up after surgical abortion is not a standard protocol despite a similar failure rate to medical abortion.[4] The number of visits to the clinic might be an important factor in the acceptability of medical abortion. Some studies have indicated that medical abortion is associated with more negative experiences of care and lower acceptability than surgical abortion, which has been attributed partly to the need for more follow-up visits.[6] Use of urine hCG tests with sensitivity of around 1000 IU/L to enable women to eliminate clinical visits has been suggested.[5,7] If such a test was proven to be safe and effective, many women would not need to attend follow-up clinic visits.[7]

Women with complications arising from an abortion generally seek health care, especially if they have received adequate counselling. Continuing viable pregnancy after a failed medical abortion, however, might remain unnoticed until after the legal limit for induced abortion has passed. For this reason, a reliable method for excluding continuing pregnancy is important. A review by Grossman and Grindlay[8] showed varying sensitivity of self-assessment to identify continuing pregnancy. Assessment of outcomes with ultrasonography or testing for hCG in serum are the most accurate methods but require substantial resources. High-sensitivity urine hCG pregnancy tests, which can

detect hCG concentrations lower than 25 IU/L, are of limited value for follow-up because results can remain positive for several weeks after termination of pregnancy.[9,10] Semiquantitative urine hCG tests with upper cutoff concentrations of 1000 IU/L or higher combined with incrementally lower cutoff concentrations down to as low as 5 IU/L have been developed and have the potential to identify complete abortion within a short time; falling hCG concentrations register as a negative result for pregnancy with these tests.[11,12]

We did a non-inferiority study to assess whether a commercially available semiquantitative urine hCG test for self-assessment of abortion outcome would be as effective and manageable as outpatient follow-up after medical abortion.

Methods

Study design and patients

Between Aug 16, 2011, and Jan, 31, 2013, all women who requested a medical termination of pregnancy of up to 63 days' gestation (crown-to-rump length 22·4 mm or less[13]) in four clinics (three in teaching hospitals) in Austria (Vienna), Finland (Helsinki), Norway (Oslo), and Sweden (Stockholm) were informed of this study. Eligible women were aged 18 years or older and had a documented confirmation of evolutive intrauterine pregnancy (ie, visible intrauterine yolk sac or fetal heartbeat on ultrasonographic examination). Exclusion criteria were known contraindications to medical abortion drugs or to self-administration of misoprostol at home (eg, women with learning difficulties, serious mental illness, or those without a person who could be with them during the abortion), unwillingness to be contacted for follow-up, and symptoms and signs of ectopic pregnancy or non-viable pregnancy. The local or national ethics review committee approved the protocol for each participating centre. All women gave written informed consent.

Randomisation

The coordinating centre at Karolinska University Hospital, Stockholm, Sweden, provided unique centre-specific randomisation numbers, generated by computer in blocks of ten. Women were assigned to treatment by study nurses in Helsinki, Oslo, and Stockholm and by a study doctor in Vienna by opening sealed, opaque, sequentially numbered envelopes that corresponded to the randomisation list. Women were allocated in a 1:1 ratio to routine clinical follow-up 1–3 weeks after abortion or to self-assessment with a urine hCG test at home 1–3 weeks after abortion.

Procedures

At the initial visit in the outpatient clinic, all women were given 200 mg mifepristone to take immediately and 800 μg misoprostol to take by vaginal self-administration at home 24–48 h later. Appropriate methods of contraception were discussed and prescribed (if required) and a plan for use after the abortion was agreed. For women in the routine follow-up group a visit at the clinic was scheduled with a qualified practitioner (a nurse in Sweden and Finland and a gynaecologist in Austria and Norway) 1–3 weeks later to assess the outcome of abortion, according to the clinic's standard routine: use of a low-sensitivity urine hCG test, measurement of hCG in serum, or ultrasonography. During the follow-up appointment women were asked whether they would have any preferences for treatment if they were to have an abortion in the future and whether they had started using contraception as agreed. In the self-administration group, women were asked to self-assess outcome 1–3 weeks after abortion with a two-step urine hCG DUO test (Vedal Lab, Alençon, France), which has two dectection thresholds of 5 and 1000 IU/L (figure 1). A telephone consultation with the clinic was scheduled for within 1 month of the initial consultation. During the telephone interview women were asked whether they had noticed expulsion of products of conception, if the hCG test was negative for either the 1000 IU/L or 5 IU/L concentrations, if the home test was easy to use, what their preferences for treatment would be if they wanted an abortion in the future, and whether they had started using contraception as agreed.

Women were told they could contact the clinic at any time if they had any questions or health concerns. The patients' charts for both groups were reviewed after 3 months to see whether any women underwent additional visits because of abortion-related complications. Data were recorded initially on individual printed case report forms then entered in digital case report forms available via a centre-specific module at the Reproductive Health Research website of Karolinska Institutet. Data quality was assessed by computer-generated verification of consistency and by operator reviews.

For the **protocol of this trial** see http://ki.se/en/people/krigem

Outcomes

The primary outcome was the percentage of women with complete abortion and clinical efficacy. Complete abortion was defined as no requirement for further surgical or medical intervention within 3 months to complete the abortion. Clinical efficacy was assessed by monitoring of unplanned or emergency admissions for adverse events, complications reported during the telephone consultations, and review of hospital charts. Secondary outcomes were loss to follow-up, additional

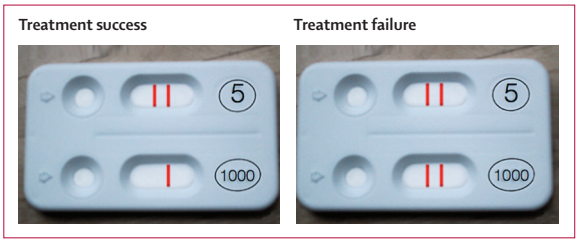

Figure 1: **Semiquantitative urine human chorionic gonadotropin test, with two detection thresholds of 5 and 1000 IU/L**

visits, additional telephone consultations, acceptability, and initiation of agreed contraception, as reported via questionnaires completed at the follow-up outpatient visit or in responses during the telephone follow-up consultation.

Statistical analysis

Data were maintained and statistical analysis was done by the coordinating research organisation at Karolinska Institutet. All statistical analyses were done in R (version 2.15.3) and SAS (version 9.4).

To test the hypothesis that self-assessment of abortion with semiquantitative urine hCG tests would be as effective and safe as routine follow-up, we set the margin of non-inferiority to an absolute difference between groups of five percentage points in event rate. We based this cutoff on what we deemed to be a clinically important difference and on ethical criteria, cost, and feasibility.[14] The rate of complete abortion with mifepristone and misoprostol reported in practice is 92%[14,15] and, therefore, to achieve 80% power and a two-sided 95% CI with α set at 0·025 for the non-inferiority hypothesis, we estimated that 925 women would need to be assessed. Thus, with an assumed loss to follow-up of 20%, we aimed to enrol 1200 women (600 in each group).[16] We found during recruitment, however, that the numbers of women eligible and willing to participate in some study centres were low and, therefore, stopped recruitment before 1200 women could be enrolled. To minimise the effect of missing data on the primary outcome, we reviewed patients' hospital charts 3 months after abortion. Risk differences and 95% CIs were calculated for the primary endpoint with a binomial model with an identity link (PROC GENMOD in SAS).[17] To take into account possible heterogeneity between countries, we did the same analysis with country as a factor.

Descriptive statistics are presented for all other variables. Categorical variables are presented with absolute and relative frequencies. If appropriate, distributional differences between the two groups were calculated with Fisher's exact test, in which superiority hypothesis testing is applied. Since some data were missing for the secondary outcome, we did two sensitivity analyses where the missing values were imputed: one assuming that all patients with missing values preferred the assigned method of follow-up and one assuming that all patients with missing values preferred the other method of follow-up. Continuous data are presented as median (range) or mean (SD).

The intention-to-treat population was defined as all randomised patients with data for the primary outcome except for those who withdrew consent to participate. The per-protocol population was the intention-to-treat population excluding women who had major protocol violations (eg, crossover in assessment method). The primary analysis was done in the per-protocol population, supplemented by intention-to-treat data. All other analyses (secondary outcomes and baseline characteristics) were assessed in the intention-to-treat population.

The level of significance was set to 5% two-sided. Of note, although we did only one primary analysis, we made no adjustment for multiplicity and, therefore, the findings for the secondary outcomes and other analyses should be interpreted with care. One interim data analysis was done in June, 2012, after the recruitment of 394 women, to report to the funders. Safety data were reviewed descriptively without any formal statistical testing and no changes were made to the study design after this analysis. This trial is registered with ClinicalTrials.gov, number NCT01487213.

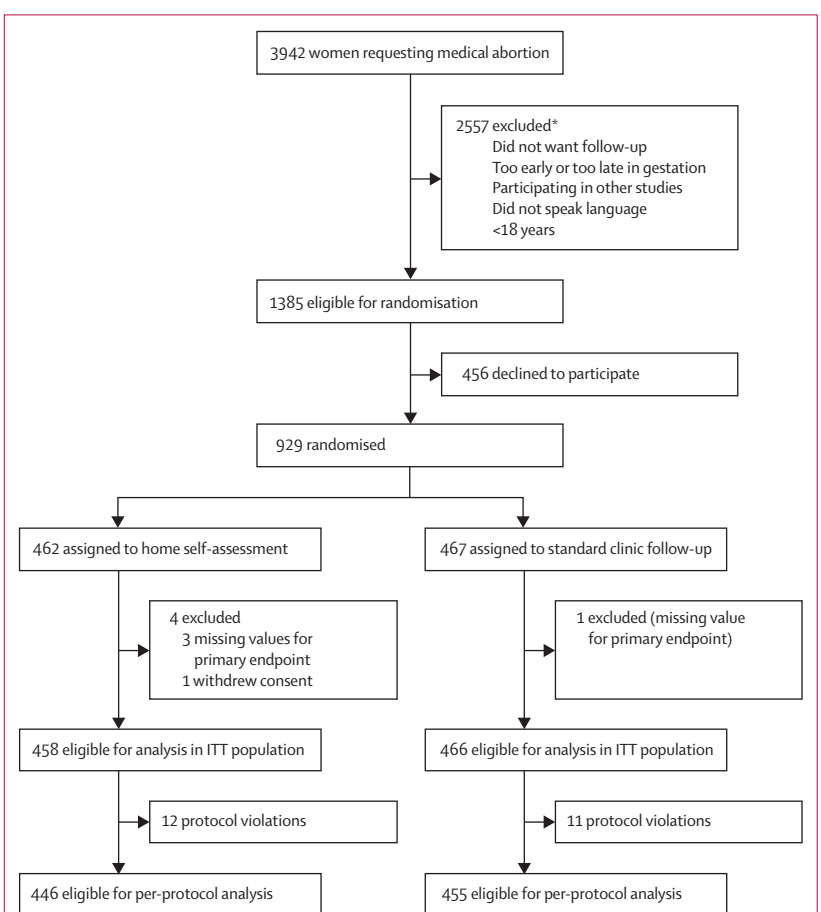

Figure 2: **Trial profile**
ITT=intention to treat. *Data missing for some patients and, therefore, exact numbers are unavailable. Around 90% of excluded women gave did not want follow-up, too early or late in gestation, and did not speak language as reasons.

Role of the funding sources

The funders had no role in study design, data interpretation, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Of 3942 women who requested termination of pregnancy, 1385 (35%) were eligible for inclusion in the study. 456 (33%) eligible women declined to participate and, therefore, 929 were randomised (figure 2). The intention-to-treat population comprised 924 women (n=466 in the routine follow-up group and n=458 in the self-assessment group). Protocol violations were reported in 11 women in the routine follow-up group (two crossovers, five who received misoprostol in the clinic, and four who miscarried before taking misoprostol) and 12 in the self-assessment group (nine follow-up crossovers and three who received misoprostol at the clinic). Thus, the per-protocol population comprised 901 women (n=455 in the routine follow-up group and n=446 in the self-assessment group).

The baseline characteristics were similar in the two groups (table). Complete abortion without any additional treatment within 3 months was reported in 432 (95%) of 455 in the routine follow-up group and 419 (94%) of 446 women in the self-assessment group, which was well within the non-inferiority margin (crude risk difference –1·0, 95% CI –4·0 to 2·0). The corresponding risk difference in the intention-to-treat population was –0·8 (95% CI –3·8 to 2·3). Adjustment by country did not substantially affect the risk difference (figure 3). The rate of additional surgical treatment after abortion was 20 (4%) in the routine follow-up group and 17 (4%) in the self-assessment group (p=0·738). The main reasons for surgery were sustained bleeding, incomplete abortion, or both. 12 women received additional doses of misoprostol to treat sustained or heavy bleeding (four [0·9%] in the routine follow-up group and eight [1·8%] in the self-assessment group). No cases of continuing pregnancy were detected in the routine follow-up group. Three (0·7%) women in the self-assessment group had continuing pregnancies that were undetected by the urine hCG test, all of which were discovered in the second trimester. The women were offered repeat doses of mifepristone and misoprostol and achieved complete abortion in hospital with no further complications. These women were included in the primary analysis as incomplete abortions.

Nine women had clinically diagnosed infections, eight (1·8%) in the routine follow-up group and one (0·2%) in the self-assessment group (p=0·038). Five of those in the routine follow-up group and the woman in the self-assessment group were treated with oral antibiotics and the remaining three were treated with vacuum aspiration and antibiotics. All nine women were included in the primary analysis. Two women (one in each group) received iron supplements because of heavy bleeding, but no haemoglobin concentrations were recorded.

The secondary outcomes analysis showed that 108 (23%) women in the routine follow-up group and 90 (20%) in the self-assessment group were lost to follow-up (p=0·199). No significant differences were seen between groups in the numbers of women who had at least one additional telephone consultation (65 [19%] of 348 in the routine follow-up group *vs* 68 [20%] of 346 in the self-assessment group, p=0·773) or clinic visit (24 [7%] of 344 *vs* 30 [9%] of 344, p=0·479). 310 (91%) of 340 women in the self-assessment group found the semiquantitative urine hCG test easy to use. Compared with women in the routine follow-up group, a significantly larger proportion of

	Routine clinical follow-up (n=466)	Self-assessment follow-up (n=458)
Country		
Austria	87 (19%)	84 (18%)
Finland	40 (9%)	40 (9%)
Norway	150 (32%)	150 (33%)
Sweden	189 (41%)	184 (40%)
Age (years)		
<20	19 (4%)	21 (5%)
20–24	130 (28%)	113 (25%)
25–29	126 (27%)	135 (29%)
30–34	90 (19%)	102 (22%)
35–39	66 (14%)	54 (12%)
40–44	30 (6%)	25 (6%)
45–50	3 (1%)	3 (1%)
Median (range) BMI (kg/m²)	23 (13–43)	22 (15–59)
Delivery history		
Mean (SD) parity	0·8 (1·0)	0·8 (1·1)
Mean (SD) number of vaginal deliveries	0·7 (1·1)	0·8 (1·0)
Caesarean delivery	39/404 (10%)	37/411 (9%)
Miscarriage	53/408 (13%)	49/408 (12%)
Ectopic pregnancy	5 (1%)	7 (2%)
Surgical abortion	118/407 (29%)	106/408 (26%)
Medical abortion	137/391 (35%)	128/376 (34%)
Study pregnancy		
Median (range) duration (days)	46 (28–63)	46 (34–63)
<49 days	286/454 (63%)	284/444 (64%)
49–56 days	104/452 (23%)	112/448 (25%)
56–63 days	67 (14%)	51 (11%)
Genital infection at initial assessment	27 (6%)	26 (6%)

BMI=body-mass index.

Table: **Baseline characteristics**

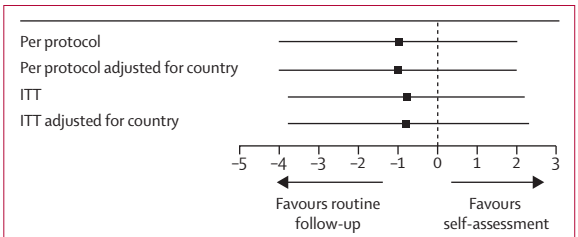

Figure 3: **Risk difference between groups for the primary outcome**
ITT=intention to treat.

women in the self-assessment group stated that they would prefer self-assessment at home to routine clinical follow-up if they were to have an abortion in future (272 [82%] of 330 *vs* 190 [59%] of 323, p<0·0001). After imputing all missing values as a preference for the assigned follow-up method, the results remained significantly in favour of self-assessment (400 [87%] of 458 *vs* 333 [71%] of 466, p<0·0001). This result also remained significant when preference for the other follow-up method was assumed (272 [59%] of 458 *vs* 190 [41%] of 466, p<0·0001). A significantly lower proportion of women in the routine follow-up group than those in the self-assessment group expressed satisfaction with contraceptive counselling (323 [92%] of 350 *vs* 351 [98%] of 358, p=0·001). Nevertheless, the proportions of women who had started the agreed method of contraception did not differ between groups (205 [56%] of 366 *vs* 202 [55%] of 369, p=0·882).

Discussion

Self-assessment of the outcome of medical abortion with a semiquantitative urine hCG test was not inferior to routine clinical follow-up and no differences were seen in complication rates. Our findings indicate that the outcome of medical abortion can be managed by alternative protocols. Satisfaction with follow-up method was significantly greater for self-assessment than for routine follow-up.

A large number of women who were seeking abortion did not want to be included in the study because they did not want any follow-up after the abortion. No clinical follow-up is becoming increasingly common and will be seen even more frequently when medical abortion becomes the standard method. We do not believe, however, that our study was affected by recruiting bias towards self-assessment.

The semiquantitative urine hCG test used in this study is commercially available in Europe and, therefore, its use reflects the real-world setting. The most serious complication of self-assessment was the failure of the test to detect three continuing pregnancies (two in Norway and one in Finland). All three women maintained that they had followed the instructions for use and had interpreted the results as treatment success. No further details of the testing situation could be retrieved in these cases and, therefore, we are unable to differentiate between user and test failure. All three women subsequently chose to undergo a second-trimester medical abortion at 17–19 weeks' gestation, in line with routine practice for second-trimester abortions in Nordic countries. Two of the women stated that they would choose the same follow-up method if they were to have another abortion, whereas the third woman said that she would prefer routine clinical follow-up, but would have a medical abortion again with self-administration of misoprostol at home.

On the basis of our findings, we assume that continuing pregnancies in the self-assessment group would have been diagnosed if the women had attended routine clinical follow-up instead. Whether a different time interval to self-assessment would alter results in the absence of symptoms of continued pregnancy should be investigated further. Perriera and colleagues[18] showed that self-assessment of pregnancy symptoms without a pregnancy test within 1 week and a high-sensitivity pregnancy test within 4 weeks of abortion identified continuing pregnancy. 27 (23%) of 116 patients in that study had positive pregnancy tests at 4 weeks. Semiquantitative pregnancy tests have the potential advantages of confirming treatment success after a short time and being more specific than self-assessment of pregnancy symptoms. Non-commercial semiquantitative urine hCG tests assessed in studies confirmed complete abortion and identified complications.[11,12] Telephone follow-up with a checklist of symptoms and self-assessment with low-sensitivity urine pregnancy testing after early medical abortion have proved as accurate as clinical follow-up after introduction into abortion services.[19,20] Surgical abortion also carries a risk of treatment failure.[21] An integral part of counselling before abortion, therefore, must include information on the risk of continuing pregnancy to encourage women to contact the service provider for follow-up if they have concerns.

Although we curtailed enrolment of women after 929 had been randomised, we kept loss to follow-up for the primary outcome to a minimum by reviewing hospital charts for complications 3 months after abortion. Consequently, the intention-to-treat population comprised 924 women, which is one less than the estimated original requirement. Thus, this study was adequately powered to detect a difference between groups in the primary outcome on the basis of the initial sample size calculation.

Despite the reduced numbers of women available for some of the secondary outcomes analyses owing to loss to follow-up, we feel that the primary outcome was accurately recorded because the study centres were the sole providers of medical abortion services and care for abortion-related complications in their respective regions. Additionally, patients' details could be obtained by a common hospital records system, which reduced the loss to follow-up for the primary outcome to four (0·4%) of 928 women.

The only valid reason for a follow-up in the absence of clinical symptoms after a medical abortion is to exclude a continuing viable pregnancy. High-sensitivity urine hCG tests show positive results in most women 2–3 weeks after abortion,[22] whereas low-sensitivity urine hCG tests can confirm complete abortion within a shorter time period. The use of these tests would be especially desirable in resource-poor settings or in sparsely populated regions, where access to abortion services and ultrasound examination might be limited. Reduced reliance on ultrasonography would also decrease the number of unnecessary interventions to which women

Panel: Research in context

Systematic review

In addition to using the latest WHO and Royal College of Obstetricians and Gynaecologists guidelines for induced abortion,[1,4] we searched PubMed for published studies about medical abortion, home use of misoprostol, semiquantitative pregnancy tests, and follow-up after medical abortion, published up to May 6, 2014. We used the free-text search terms "abortion", "misoprostol", "mifepristone", "early medical abortion", "first trimester medical abortion", "induced abortion", "medical abortion versus", "assessment", "review", "protocol", "self-administration", "self-performed", "acceptability", "semi-quantitative", "follow-up", "pregnancy test", "routine", "acceptability", "home", "simplif*", "fail", and "complications" in various combinations. We also did a search with the Medical Subject Headings "abortion induced AND feasibility studies". We applied no language or date restrictions. We identified one randomised study meeting these criteria[27] and four observational studies and two review articles on the use of semiquantitative, low-sensitivity or high-sensitivity urine pregnancy tests for follow-up after medical abortion.[10,11,19–21,26] The evidence suggested that the home use of urine pregnancy tests would be a feasible alternative to clinical follow-up after early medical abortion. In particular, low-sensitivity qualitative urine pregnancy tests could verify complete medical abortion within 2–3 weeks. We found no randomised studies comparing women who assessed the treatment outcome themselves after medical abortion with those who attended routine clinical assessment by health-care staff with commercially available low-sensitivity urine tests.

Interpretation

Self-assessment with a commercially available low-sensitivity semiquantitative urine pregnancy test was non-inferior as a means of verifying successful medical abortion after home administration of misoprostol in real-world clinical settings. Three missed continuing viable pregnancies in the self-assessment group suggest that the urine human chorionic gonadotropin test we used would need to be improved before we could recommend its use in clinical practice.

are exposed, frequently owing to ultrasound examination by inexperienced providers.[15,23,24] Nevertheless, the semiquantitative urine hCG test we used would need to be improved before we could recommend its use in clinical practice. The three continuing pregnancies suggest that the rate of false-negative results should be verified for the 5 and 1000 IU/L test to improve information for patients and ease of use.

Although checklists for telephone interviews are useful, they do not improve outcomes of self-assessment with a semiquantitative urine hCG test after medical abortion.[25,26] On the basis of our findings and those from studies of more-complex semiquantitative tests,[11,12] a simpler test with just one cutoff concentration might be easier for women to use and reduce the risk of errors in interpretation of results. A test that can be used within 1–2 weeks of abortion will be crucial to detect continuing pregnancies while first-trimester abortion is still possible.

By the time of follow-up, around half of the women in the two groups had started to use contraception as agreed before abortion. Contraceptive counselling presents a particular challenge in women seeking termination of pregnancy, as many do not consider the risk of a subsequent pregnancy so soon after abortion. Grossman and colleagues[3] argued that family planning services should not be inflexibly bundled with postabortion care. To wait until a follow-up visit to select a contraceptive method is inappropriate, and women should be counselled to start using contraception on the same day or on the day after abortion. Thus, we propose that access to contraceptive counselling and services should be offered before abortion.

This study was done in accordance with the WHO safe abortion guidance,[1] which recommends that abortion should be simplified to improve access. Although simplification is crucial in low-income settings, it is probably also of relevance to high-income settings to reduce the need for medical resources and shorten waiting times. Most importantly, the number of women who do not return for clinical follow-up is increasing. Self-assessment offers an important alternative for women who do not wish to or who cannot return for follow-up (panel). Women need to be counselled about the risk of continuing pregnancy and any strategy for self-assessment will need to be carefully assessed for test and user performance before introduction.

Contributors

KSO contributed to the study conception and design and drafting of the report. EQ contributed to the study design, data acquisition, and drafting of the report. CF contributed to the study conception and design, data acquisition, and commented on the draft of the report. OH contributed to the study design, data acquisition, and drafting of the report. LB was responsible for data analysis and interpretation, and commented on the draft of the report. KG-D contributed to the study conception and the design of the study, interpretation of data, and commented on the draft of the report.

Declaration of interests

We declare no competing interests.

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